

Inventor: Indu Parikh
U.S. Serial No.: 09/282,471
Filing Date: March 31, 1999

Attorney Docket No.: 28069-547CIP2
(Formerly: 401865/SKYEPHARMA)

REMARKS/ARGUMENTS

In this Amendment, claims 33-36, 38-42, 45-48, 50 and 52 are currently amended. Claims 37, 49, 51, 53 and 54 are canceled without prejudice or disclaimer; claims 55-67 are newly added; and claims 43 and 44 stand withdrawn as being drawn to a non-elected species. In addition, the specification has been amended for clarity. No new matter has been introduced into the application by virtue of the amendments to the specification, or by the amended and new claims. The currently amended claims further generally contain formal or stylistic changes to the claim language.

Support for the amended and new claims is found throughout the specification of the instant application and in the prior claims. Specifically, in amended claim 1, support for one, or a combination of, the methods of reducing particle size is found in the instant specification on page 5, first paragraph, lines 3-6, as well as on page 7, paragraph 3, lines 1-4.

Accordingly, claims 33-36, 38-42, 45-48, 50, 52 and 55-67 are currently pending in this application.

The claims fulfill the requirements of 35 U.S.C. § 112, first paragraph

Claims 33-42 and 45-54 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. According to the Examiner, the instant specification does not provide support for the expressions “for reducing the initial average particle size” and “volume weighted mean particle size value that is about 50% smaller than particles produced without the presence of the surfactant”.

Applicant respectfully disagrees with this rejection and submits that the specification as filed provides full support for the recited claim language, as specifically evidenced by the following:

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On page 4, second full paragraph under “Description of the Invention”, the instant specification states that “[t]he use of a surface modifier or combination of surface modifiers in addition to a phospholipid is characterized by its ability to result in volume weighted mean particle size values that are (i) approximately 50% smaller than what can be achieved using phospholipid alone without the use of a surfactant with the same energy input ...”. In addition, on page 7, first paragraph, lines 1-3, the instant specification teaches that “... some of the functions of the second surface modifier(s) [i.e., the non-ionic, anionic, or cationic surfactant] as it relates to this invention are (a) allowing the formation of microparticles about 50% or smaller than the size produced with phospholipid alone, ...”.

Also on page 4, second full paragraph under “Description of the Invention”, it is further stated that “... we were surprised to observe a significant reduction in particle size with the addition of the surfactant.” Additionally, on page 5, first paragraph, lines 1-4, the instant disclosure states that “[p]hospholipid and surface modifier(s) are adsorbed onto the fenofibrate particle surfaces in sufficient quantity to retard particle growth, reduce the initial average particle size of from 5 to 100 μm to micron and submicron size particles by one or combination of methods known in the art ...”.

In view of the foregoing, Applicant submits that the instant disclosure provides direct support for the recited claim language. Accordingly, withdrawal of the §112, first paragraph, rejection is respectfully requested.

The claims as presently amended are novel and unobvious

Based on this record, Applicant respectfully submits that the presently amended claims are both novel and unobvious in view of the disclosures of the cited relevant art, taken alone or in combination.

It has been previously argued that Applicant’s method of preparing fenofibrate microparticles is patentably distinct from methods described in the cited relevant art, considered

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alone or in combination. More particularly, the cited relevant art, alone or in combination does not teach or suggest Applicant's method, considered as a whole, which involves mixing of fenofibrate particles with phospholipid and at least one non-ionic, anionic, or cationic surfactant to form a mixture, either prior to or during the reduction of particle size, by one or more of sonication, milling, homogenization, microfluidization, antisolvent and solvent precipitation, and then applying energy to the mixture sufficient to produce fenofibrate microparticles having a volume-weighted mean particle size that is about 50% smaller than particles produced without the presence of the surfactant using the same energy input.

Applicant has surprisingly discovered that the presence of both phospholipid and the described classes of surfactant prior to, or at the time of, particle size reduction results in a significant reduction of particle size, compared with phospholipid alone, or phospholipid with other than the described classes of non-ionic, anionic, or cationic surfactants. (See, e.g., the instant specification on page 4, second paragraph, lines 5-9.) In accordance with the present invention, the presence of phospholipid and one or more non-ionic, anionic, or cationic surfactant absorb to the surfaces of fenofibrate, thereby modifying the surfaces and allowing smaller, more stabilized fenofibrate microparticles to be formed. (See, e.g., the instant specification on page 4, fourth paragraph, lines 2-4.)

The advantages and surprising results afforded by the presently claimed methods are not disclosed or suggested by the cited relevant art, either alone or in combination. It is submitted that, when considered in their entirety, the presently amended claims directed to (1) novel methods involving mixing fenofibrate particles with phospholipid and one or more non-ionic, anionic, or cationic surfactants (i.e., second surface modifier), (e.g., claim 1), and (2) novel methods involving mixing fenofibrate particles with phospholipid and one or more particularly elucidated types of non-ionic, anionic, or cationic surfactants (e.g., claim 55) are patentably distinguished over the relevant art.

The relevant art, both alone and in combination, neither teaches nor suggests Applicant's methods as a whole, or the advantages provided to the art by these methods. Consequently, the

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presently amended claims, directed to methods of varying scope, are new and unobvious in view of the teachings of the relevant art for the reasons of record.

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CONCLUSION

Applicant respectfully submits that this application is now in condition for allowance. An action progressing this application to issue is courteously urged.

Should any additional fees be deemed to be properly assessable in this application for the timely consideration of this Amendment and response, or during the pendency of this application, the Commissioner is hereby authorized to charge any such additional fee(s), or to credit any overpayment, to Deposit Account No. 50-0311, Reference No. 28069-547CIP2, Customer No. 34537.

If the Examiner believes that further discussion of the application would be helpful, he is respectfully requested to telephone the undersigned at (212) 692-6742 and is assured of full cooperation in an effort to advance the prosecution of the instant application and claims to allowance.

Respectfully submitted,

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